Auditing a Change Management System

Goals

When you have completed this unit, you should be able to:

- Perform an audit of a change management system.
- Use a range of tools and information, including the contents of this unit and the internet to support the audit of a change management system.
- Understand and apply appropriate GMP standards/regulations to an audit of a change management system.
- Recognize compliance or non-compliance of a change management system to applicable regulations.

Definitions

Change Control: A formal process by which qualified representatives of appropriate disciplines review (including technical and operational impact assessment), authorize, approve and close proposed or actual changes to facilities, systems, equipment and processes to ensure that they are maintained in a controlled manner.

Explanation of Topic

Introduction

Planned changes may be proposed to a starting material, product component, process equipment, process environment (or site), method of production or testing or any other change that may affect product quality or reproducibility of the process. Written procedures should be in place to describe the actions to be taken if such a change is proposed. Change control procedures should ensure that sufficient supporting data are generated to demonstrate that the revised process will result in a product of the desired quality, consistent with the approved specifications.

All changes that may affect product quality or reproducibility of the process should be formally requested, documented and accepted. The likely impact of the change of facilities, systems and equipment on the product should be evaluated, including risk analysis. The need for and the extent of re-qualification and re-validation should be determined and the rationale captured in the documentation.

Basic Components of a Change Management System

If a piece of equipment or a process needs to be modified, it should follow an established and approved change control process as outlined in a detailed approved procedure. This procedure should include direction and guidance and answer the following questions:

- Ø What is the proposed change?
- Ø How will it be implemented?
- Ø Who are the necessary parties to approve it?

requirements and responsibilities within the change as they apply to their area. The **second** is that they verify the accuracy of all functions directly affecting their area of responsibility. The **last** responsibility is to provide the required resources to facilitate implementation of the change, whether specific or implied.

If changes to the proposal document are needed prior to approval, the Change Coordinators, Initiators and Approvers should work together to facilitate. If during the review process a change is determined as not needed or additional changes or modifications to the proposal are warranted, the process may have to be reinitiated or require the generation of additional change requests.

Only after documented approval is attained can implementation of any change commence.

Change Implementation

The change as described in the approved request can proceed to implementation according to the plan. If needs for additional changes are encountered during the implementation process, that were not approved as part of the original proposal, then additional change request approvals may be necessary.

Assessment of the Change as Implemented

Procedures should be in place to evaluate and assess implemented changes. The intention is to provide confirmation the original change had the intended effect based on the original justification. For a minor or evident change the assessment can be performed as part of the implementation process. However, for changes that are wider in scope and impact, the assessment could be done initially and/or after appropriate data points are available (based on data generation).

Change Closure

The change request is closed when the change has been implemented, documentation updated, outstanding actions completed, follow-up assessments performed and concluded as effective, and regulatory commitments have been communicated.

Summary

Any change that affects a GMP system or the regulatory compliance of a product or process is to be controlled through a formal approved change control system/process. The change control system should include information from the submission, through to the implementation and effectiveness assessment of the change.

A representative of the Quality unit must approve proposed changes that have the potential to have an impact on the quality, purity, identity, and safety of a drug product. All changes that have regulatory impact must be reviewed and assessed with respect to the product submission by Regulatory personnel.

Changes are usually categorized and tracked. Depending on the site criteria, changes may be prioritized differently and be subjected to different types of implementation strategies, as well as proposal and approval. Quality unit involvement should be early on in the process, through to final closure.